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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,695	08/08/2006	Friedbert Wechs	2037.7	8355

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EXAMINER	
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ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,695	WECHS ET AL.	
	Examiner	Art Unit	
	MADELINE GONZALEZ	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5 and 7-19* is/are pending in the application.

4a) Of the above claim(s) *10-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,7-9,18 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

In response to applicant's amendment dated June 29, 2009

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4, 5, 7-9 and 19 are finally rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wang et al. (U.S. 6,565,782) [hereinafter Wang].

With respect to **claims 1, 8, 9 and 19**, Wang discloses membrane having:

- a hydrophilic, watter-wettable membrane being based on;
    - a hydrophobic first polymer, such as polysulfone polymer (aromatic sulfone polymer) (see col. 5, lines 52-54); and
    - a hydrophilic second polymer such as polyvinylpyrrolidone (see col. 5, lines 54-55);

- possessing an open-pored, integrally asymmetric structure across its wall, with a porous separating layer on its inner surface facing the lumen and an open-pored supporting layer (see col. 5, lines 31-38); and
- whereby the hollow-fiber membrane in the dry state is free from pore-stabilizing additives in the membrane wall (see col. 10, line 27 through col. 13, line 48).

Wang **lacks** the specific thickness of the separating layer, the specific ultrafiltration rate in albumin solution, the minimum sieving coefficient for cytochrome c and the maximum sieving coefficient for albumin. However, Wang teaches a membrane made of the same material as claimed by applicant and a similar process of making the membrane (see col. 10, line 27 through col. 13, line 48). It is therefore inherent that the membrane has the same ultrafiltration rate and sieving coefficients claimed by applicant, absent evidence to the contrary. Furthermore, it would have been obvious to obtain the specific ultrafiltration rate and sieving coefficients for the membrane disclosed by Wang since the court have held that "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation (*see In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)*).

With respect to **claim 4**, Wang discloses wherein the aromatic sulfone polymer is polysulfone (see col. 5, lines 52-54).

With respect to **claim 5**, Wang discloses wherein the hydrophilic first polymer is a polysulfone or a polyethersulfone (see col. 5, lines 52-54).

With respect to **claim 7**, Wang discloses wherein the supporting layer extends from the separating layer across essentially the entire wall of the hollow-fiber membrane, has a sponge-like structure and is free from finger pores, as shown in Figs. 1C and 2A.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 18 is finally rejected under 35 U.S.C. 103(a) as being unpatentable over a combination of Wang (U.S. 6,565,782) and Chu et al. (U.S. 4,604,208) [hereinafter Chu]

With respect to **claim 18**, Wang teaches that the membrane can be further modified by charge modification of the membrane surface in order to remove or exchange ions as a step in a filtration process (see col. 7, lines 27-37). Wang **lacks** a polyelectrolyte with negative fixed charges physically bound in the separating layer.

Chu teaches an anionic charge modified microporous membrane wherein a polyelectrolyte with negative charges is physically bound in the separating layer (see col. 9, lines 59-66) in order to enhance the filtration membrane performance of the membrane for charged particulate contaminants without decreasing the pore size if the membrane (see col. 5, lines 28-35). It would have been obvious to provide the membrane disclosed by Wang with a polyelectrolyte with negative fixed charges physically bound in the separating layer, as taught by Chu, in order to enhance the filtration membrane performance of the membrane for charged particulate contaminants without decreasing the pore size if the membrane (see col. 5, lines 28-35) and since Wang is already suggesting that the membrane can be further modified by charge modification of the membrane surface in order to remove or exchange ions as a step in a filtration process (see col. 7, lines 27-37).

Double Patenting

Claims 1, 4, 5, 7-9, 18 and 19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/588,696. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claim 1 has an ultrafiltration rate in albumin solution in the range of 25 to 60 ml/(h m^2 mmHg), whereas the copending claim 1 has an ultrafiltration rate in the range of 5 to 23.5 ml/(h m^2 mmHg). However, it appears that the apparatus in the instant claims would function at

a lower ultrafiltration rate as there is no structural difference between the membranes. The sieving coefficient of cytochrome c in the copending claim 1 is expressed by a relation, whereas the instant claim discloses the sieving coefficient of cytochrome c as a minimum of 0.8. Using the ultrafiltration rate range disclosed by the instant claim 1, the relation disclosed by the copending claim 1 was satisfied in that it is higher 0.8. As further evidence that the copending and instant claims overlap in scope, and therefore are not patentably distinguishable, the copending specification discloses that the minimum sieving coefficient for cytochrome c is preferably 0.8 (Page 11, Lines 1-2). Therefore the sieving coefficient disclosed by the instant application claim 1 are within range of the relation disclosed in the copending claim 1. Instant claims 4, 5, 7-9 and 18 are identical to copending claims 3-10.

Claims 1, 4, 5, 7-9, 18 and 19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12 and 14-16 of copending Application No. 10/588,016. Although the conflicting claims are not identical, they are not patentably distinct from each other because both disclose a hollow fiber membrane with polyelectrolyte bound in the separating layer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments with respect to claims 1, 4, 5, 7-9, 18 and 19 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MADELINE GONZALEZ whose telephone number is (571)272-5502. The examiner can normally be reached on M, T, Th, F- 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Duane Smith can be reached on 571-272-1166. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/
Primary Examiner, Art Unit 1797

Madeline Gonzalez
Patent Examiner
November 10, 2009